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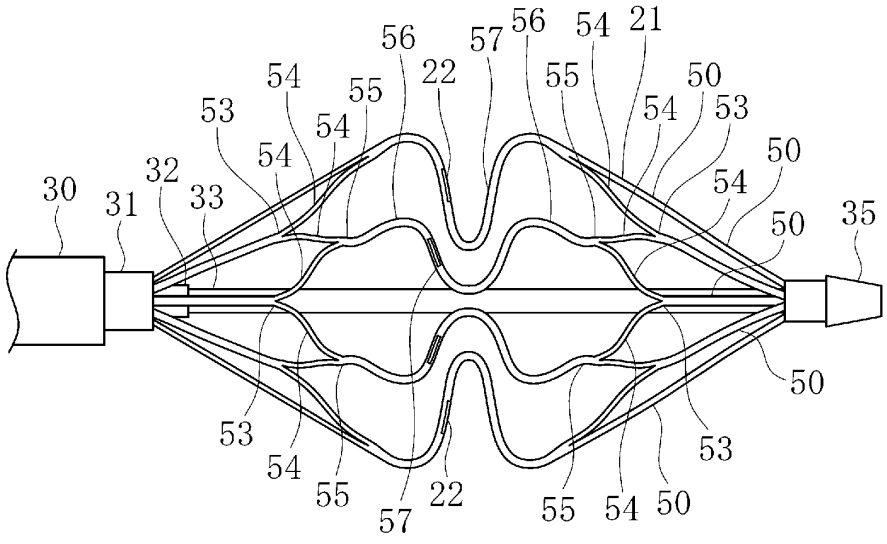
(54) MEDICAL DEVICE

(57) Provided is a medical device which can suppress torsion of a wire in a circumferential direction in an expansion body formed using the wire.

Provided is a medical device (10) which enlarges a biological tissue. The medical device (10) includes an elongated shaft portion (20) and an expansion body (21) disposed in a distal portion of the shaft portion (20). The expansion body (21) has a wire portion (50) configured to expand and contract in a radial direction, and a torsion restriction portion (54) that restricts movement of the wire portion (50) in a circumferential direction of the expansion body (21).

[Fig. 2]



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Description

Technical Field

[0001] The present invention relates to a medical device including a maintenance treatment element which applies energy to a biological tissue, and a treatment method for applying energy to a biological tissue.

Background Art

[0002] A chronic heart failure is known as one of heart diseases.
The chronic heart failure is broadly classified into a systolic heart failure and a diastolic heart failure, based on a cardiac function index.
In a patient suffering from the diastolic heart failure, myocardial hypertrophy appears, and stiffness (hardness) increases. Consequently, blood pressure increases in a left atrium, and a cardiac pumping function is degraded. In this manner, the patient may show heart failure symptoms such as a pulmonary edema.
In addition, there is another heart disease of a patient who shows the following heart failure symptom. Due to pulmonary hypertension, blood pressure increases on a right atrium side, and the cardiac pumping function is degraded.
[0003] In recent years, a shunt treatment has attracted attention. For the patients who suffer from the heart failure, a shunt (through-hole) serving as an escape route for increased atrial pressure is formed in an atrial septum, thereby enabling heart failure symptom to be alleviated. In the shunt treatment, the atrial septum is accessed using an intravenous approaching method, and the through-hole is formed to have a desired size.
For example, a medical device disclosed in PTL 1 is used as one of medical devices for performing the shunt treatment on the atrial septum.

Citation List

Patent Literature

[0004] PTL 1: US Patent No. 8,882,697

Summary of Invention

Technical Problem

[0005] According to the medical device disclosed in PTL 1, a shunt hole is enlarged using a balloon serving as an expansion body disposed in a distal portion of a shaft portion, and a through-hole is maintained by an electrode disposed in the balloon.
However, when the through-hole is enlarged, the medical device blocks the through-hole with the balloon. Accordingly, hemodynamics cannot be confirmed.
Therefore, the hemodynamics are confirmed after the balloon is removed, and thus, a therapeutic effect obtained by the through-hole cannot be immediately confirmed.
[0006] In order to confirm the hemodynamics when the through-hole is enlarged, it is conceivable that the expansion body is formed using wires to enable blood to flow from a space between the wires of the expansion body.
However, in a case where the expansion body are formed using the wires, the wires may have torsion in a circumferential direction when the expansion body expands, thereby causing a possibility that an expansion force may not be sufficiently transmitted to a biological tissue.
[0007] The present invention is made in order to solve the above-described problem, and an object thereof is to provide a medical device which can suppress torsion of wires in a circumferential direction in an expansion body formed using the wires.

Solution to Problem

[0008] According to the present invention, in order to achieve the above-described object, there is provided a medical device which enlarges a biological tissue. The medical device includes an elongated shaft portion, and an expansion body disposed in a distal portion of the shaft portion, and configured to expand and contract in a radial direction. The expansion body has a wire portion linked with the shaft portion, and a torsion restriction portion that is configured to restrict movement of the wire portion in a circumferential direction.

Advantageous Effects of Invention

[0009] The medical device configured as described above can suppress torsion in the circumferential direction when the expansion body formed using the wire expands.

Brief Description of Drawings

[0010]

[Fig. 1] Fig. 1 is a front view illustrating an overall configuration of a medical device having an expansion body according to a first embodiment.
[Fig. 2] Fig. 2 is an enlarged front view illustrating the vicinity of the expansion body.
[Fig. 3] Fig. 3 is an enlarged front view illustrating the vicinity of the expansion body which expands.
[Fig. 4] Fig. 4 is an enlarged front view illustrating the vicinity of an expansion body according to a modification example.
[Fig. 5] Fig. 5 is a flowchart of a treatment method using the medical device.
[Fig. 6] Fig. 6 is a view for describing the treatment method according to the present embodiment, and is a view for schematically describing a state where

the expansion body is disposed in a through-hole of an atrial septum, in which a biological tissue is illustrated in a sectional view and the medical device is illustrated in a front view, respectively.

[Fig. 7] Fig. 7 is an enlarged front view illustrating the vicinity of an expansion body according to a second embodiment.

[Fig. 8] Fig. 8 is an enlarged plan view illustrating the vicinity of a link portion of a wire portion.

[Fig. 9] Fig. 9 is an enlarged front view illustrating the vicinity of the expansion body which expands.

[Fig. 10] Fig. 10 is an enlarged front view illustrating the vicinity of an expansion body according to a first modification example in the second embodiment.

[Fig. 11] Fig. 11 is an enlarged front view illustrating a state where the expansion body according to the first modification example expands.

[Fig. 12] Fig. 12 is an enlarged front view illustrating the vicinity of an expansion body according to a second modification example.

[Fig. 13] Fig. 13 is an enlarged front view illustrating a state where the expansion body according to the second modification example expands.

[Fig. 14] Fig. 14 is an enlarged front view illustrating the vicinity of an expansion body according to a third embodiment.

[Fig. 15] Fig. 15 illustrates an enlarged plan view (Fig. 15(a)) illustrating the vicinity of a distal end of a proximal side wire portion forming the expansion body, an enlarged plan view (Fig. 15(b)) illustrating the vicinity of a proximal end of a distal side wire portion, and an enlarged plan view (Fig. 15(c)) illustrating a portion in which both of these are combined with each other.

[Fig. 16] Fig. 16 is an enlarged front view illustrating the vicinity of the expansion body which expands.

[Fig. 17] Fig. 17 is an enlarged perspective view illustrating the vicinity of a linking portion of a wire portion in a case where a fitting portion is configured to include a cutout portion.

[Fig. 18] Fig. 18 is an enlarged perspective view illustrating the vicinity of the linking portion of the wire portion in a case where the fitting portion is configured to include a slit hole and a thin portion.

[Fig. 19] Fig. 19 is an enlarged front view illustrating the vicinity of an expansion body according to a first modification example in a third embodiment.

[Fig. 20] Fig. 20 is a perspective view illustrating a wire portion forming the expansion body according to the first modification example.

[Fig. 21] Fig. 21 is an enlarged front view illustrating a state where the expansion body according to the first modification example expands.

[Fig. 22] Fig. 22 is an enlarged front view illustrating the vicinity of an expansion body according to a second modification example.

[Fig. 23] Fig. 23 is an enlarged front view illustrating a state before linkage and a state after linkage of the expansion body according to the second modification example.

[Fig. 24] Fig. 24 is an enlarged perspective view illustrating the vicinity of a linking portion of the expansion body according to the second modification example.

Description of Embodiments

[0011] Hereinafter, embodiments according to the present invention will be described with reference to the drawings.

In some cases, dimensional ratios in the drawings may be exaggerated and different from actual ratios for convenience of description.

In addition, in the present specification, a side on which a medical device 10 is inserted into a biological lumen will be referred to as a "distal end" or a "distal side", and an operating hand-side will be referred to as a "proximal end" or a "proximal side".

[0012] The medical device according to the embodiments described herein is configured as follows. A through-hole Hh formed in an atrial septum HA of a patient's heart H is enlarged, and further, a maintenance treatment is performed so that the through-hole Hh having an increased diameter is maintained to have an increased size.

[Medical Device having Expansion body of First Embodiment]

[0013] As illustrated in Fig. 1, the medical device 10 according to the present embodiment includes an elongated shaft portion 20, an expansion body 21 disposed in a distal portion of the shaft portion 20, and an operation unit 23 disposed in a proximal portion of the shaft portion 20.

The expansion body 21 has a maintenance treatment element (energy transfer element) 22 for performing the above-described maintenance treatment.

[0014] The shaft portion 20 has an outer shaft 31 that holds the expansion body 21 in the distal portion, and a storage sheath 30 that stores the outer shaft 31.

The storage sheath 30 is movable forward to and rearward from the outer shaft 31 in an axial direction.

In a state where the storage sheath 30 is moved to the distal side of the shaft portion 20, the storage sheath 30 can internally store the expansion body 21.

In a state where the expansion body 21 is stored, the storage sheath 30 is moved to the proximal side. In this manner, the expansion body 21 can be exposed.

[0015] A pulling shaft 33 fixed to the distal portion of the expansion body 21 is stored inside the outer shaft 31.

The pulling shaft 33 projects from the distal end to the distal side of the outer shaft 31, and a distal portion thereof is fixed to a distal member 35 disposed in the distal portion of the expansion body 21.

A proximal portion of the pulling shaft 33 is drawn out to

the proximal side by the operation unit 23.

[0016] The operation unit 23 has a housing 40 held by an operator, an operation dial 41 that can be rotationally operated by the operator, and a conversion mechanism 42 operated in conjunction with the rotation of the operation dial 41.

The pulling shaft 33 is held inside the operation unit 23 by the conversion mechanism 42.

In conjunction with the rotation of the operation dial 41, the conversion mechanism 42 can move the held pulling shaft 33 forward and backward along the axial direction. For example, a rack and pinion mechanism can be used as the conversion mechanism 42.

[0017] The expansion body 21 will be described in more detail.

As illustrated in Fig. 2, the expansion body 21 has a plurality of wire portions 50 in a circumferential direction.

The wire portions 50 are respectively configured to expand and contract in a radial direction.

The proximal portion of the wire portion 50 extends from the distal end to the distal side of the outer shaft 31. The distal portion of the wire portion 50 extends from the distal member 35 to the proximal side.

[0018] The wire portion 50 extending from a proximal portion 51 is inclined so that the diameter of the expansion body 21 increases toward a central portion, and an intermediate position toward the central portion has a bifurcated portion 53.

The wire portion 50 is divided into two thin bifurcated line 54 in a bifurcated portion 53.

The bifurcated line 54 merges with the bifurcated line 54 bifurcated from the wire portion 50 adjacent in the circumferential direction in a merging portion 55.

A central wire portion 56 is located on a central side of the expansion body 21 from the merging portion 55.

The wire portion 50 has the bifurcated portion 53 and the merging portion 55 in this way. Accordingly, the wire portion 50 is connected to the wire portion 50 adjacent in the circumferential direction by the bifurcated line 54.

The wire portions 50 adjacent to each other in the circumferential direction are connected to each other. Accordingly, when the diameter of the expansion body 21 increases, the wire portions 50 are mutually restricted in moving in the circumferential direction, and it is possible to suppress torsion of the expansion body 21. That is, the bifurcated line 54 functions as a torsion restriction portion of the expansion body 21.

Here, the description that the wire portions 50 are connected to each other includes a meaning that as in the present embodiment, one wire is bifurcated into two and the bifurcated wires merge with each other to form a shape of one wire.

That is, the wire forming the expansion body 21 is continuous from the proximal end to the distal end, and has a shape in which a portion thereof is bifurcated into the bifurcated lines 54 and the bifurcated lines 54 merge with each other.

The wire having this shape can be formed by performing laser cutting on a single metal cylindrical member.

[0019] The central wire portion 56 has a recessed portion 57 in the central portion.

The recessed portion 57 can hold the biological tissue. In the present embodiment, the recessed portion 57 grips the atrial septum HA.

[0020] In the expansion body 21, the proximal side and the distal side have a symmetrical shape around the recessed portion 57.

That is, from a distal portion 52 toward the center side, the wire portion 50 has the bifurcated portion 53, is bifurcated from the bifurcated portion 53 into the two bifurcated lines 54, and the bifurcated lines 54 merge with each other in the merging portion 55, thereby forming the central wire portion 56 having the recessed portion 57.

In the expansion body 21, the proximal side and the distal side have symmetrical shape. In this manner, a force acting along the axial direction is applied to the wire portion 50 when the expansion body 21 expands. Accordingly, the wire portion 50 is less likely to have torsion.

[0021] For example, the wire portion 50 has a shape of a flat plate cut out from a cylindrical member.

The wire forming the expansion body 21 can have a thickness of 50 to 500 μm and a width of 0.3 to 2.0 mm. However, the wire may have a diameter beyond this range. In addition, the wire portion 50 may have a circular shape in a cross section, or may have other shapes in a cross section.

[0022] A maintenance treatment element 22 is disposed in the recessed portion 57.

The maintenance treatment element 22 is disposed on a proximal side surface of the recessed portion 57.

When the recessed portion 57 grips the atrial septum HA, the proximal side surface of the recessed portion 57 is located on the right atrium side. Accordingly, energy from the maintenance treatment element 22 is transferred to the atrial septum HA from the right atrium side.

It is desirable that the maintenance treatment element 22 is disposed in a projection portion projecting from a surface of the recessed portion 57.

[0023] For example, the maintenance treatment element 22 is configured to include a bipolar electrode that receives electric energy from an energy supply device (not illustrated) serving as an external device.

In this case, electricity is supplied to the maintenance treatment element 22 disposed in the respective expansion portions 50.

The maintenance treatment element 22 and the energy supply device are connected to each other by a conducting wire (not illustrated) coated with an insulating coating material.

The conducting wire is drawn outward via the shaft portion 20 and the operation unit 23, and is connected to the energy supply device.

[0024] Alternatively, the maintenance treatment element 22 may be configured to serve as a monopolar electrode.

In this case, the electricity is supplied from a counter elec-

trode plate prepared outside a body.
In addition, the maintenance treatment element 22 may be a heating element (electrode chip) that generates heat by receiving high-frequency electric energy from the energy supply device.
Furthermore, the maintenance treatment element 22 can be configured to include an energy transfer element that applies energy to the through-hole Hh, such as a heater including an electric wire which provides heating and cooling operation or generating frictional heat by using microwave energy, ultrasound energy, coherent light such as laser, a heated fluid, a cooled fluid, or a chemical medium. A specific form of the energy transfer element is not particularly limited.

[0025] The wire portion 50 can be formed of a metal material.
For example, as the metal material, it is possible to use a titanium-based (Ti-Ni, Ti-Pd, or Ti-Nb-Sn) alloy, a copper-based alloy, stainless steel, β-titanium steel, or a Co-Cr alloy.
An alloy having a spring property such as a nickel titanium alloy may be used.
However, a material of the wire portion 50 is not limited thereto, and the wire portion 50 may be formed of other materials.

[0026] The shaft portion 20 has an inner shaft 32 inside the outer shaft 31, and the pulling shaft 33 is stored inside the inner shaft 32.
A guide wire lumen is formed in the pulling shaft 33 and the distal member 35 along the axial direction, and a guide wire 11 can be inserted into the guide wire lumen.

[0027] It is preferable that the storage sheath 30, the outer shaft 31, and the inner shaft 32 of the shaft portion 20 are formed of a material having a certain degree of flexibility.
For example, the material includes polyolefin such as polyethylene, polypropylene, polybutene, ethylene-propylene copolymer, ethylene-vinyl acetate copolymer, ionomer, and a mixture of the above-described two or more materials, fluororesin such as soft polyvinyl chloride resin, polyamide, polyamide elastomer, polyester, polyester elastomer, polyurethane, and polytetrafluoroethylene, polyimide, PEEK, silicone rubber, or latex rubber.

[0028] For example, the pulling shaft 33 can be formed of those in which an elongated wire formed of a super elastic alloy such as a nickel-titanium alloy and a copper-zinc alloy, a metal material such as stainless steel, or a resin material having relatively high rigidity is coated with a resin material such as polyvinyl chloride, polyethylene, polypropylene, and ethylene-propylene copolymer.

[0029] For example, the distal member 35 can be formed of a polymer material such as polyolefin, polyvinyl chloride, polyamide, polyamide elastomer, polyurethane, polyurethane elastomer, polyimide, and fluororesin or a mixture thereof. Alternatively, the distal member 35 can be formed of a multilayer tube containing two or more polymer materials.

[0030] As illustrated in Fig. 2, the expansion body 21 exposed outward of the storage sheath 30 is brought into an expanded state in the radial direction due to a self-expanding force thereof.
As illustrated in Fig. 3, the operation unit 23 is operated, and the pulling shaft 33 is moved to the proximal side so that the distal member 35 moves to the proximal side.
In response to the movement, the expansion body 21 further expands in the radial direction.
At this time, as described above, the expansion body 21 has the bifurcated line 54 that functions as the torsion restriction portion. Accordingly, the expansion body 21 can expand without any torsion in the circumferential direction.
In this manner, the maintenance treatment element 22 can suppress positional displacement of the maintenance treatment element 22 and a decrease in a holding force of the recessed portion 57.
In addition, the pulling shaft 33 is moved to the distal side in a state illustrated in Fig. 3. Accordingly, the expansion body 21 can return to a state illustrated in Fig. 2.

[0031] In addition, as a modification example of the expansion body 21, as illustrated in Fig. 4, the bifurcated line 54 may be a separate member from the wire portion 50 on the proximal side, the wire portion 50 on the distal side, and the central wire portion 56. All of these may be linked with each other by welding.
In this case, the bifurcated line 54 may have the thickness the same as that of the wire portion 50 on the proximal side, the wire portion 50 on the distal side, and the central wire portion 56, or may have a different thickness.
In addition, the wire portion 50 on the proximal side and the wire portion 50 on the distal side have the same thickness, but may have different thicknesses.

[Treatment Method Using Medical Device of First Embodiment]

[0032] A treatment method using the medical device 10 will be described.
The treatment method according to the present embodiment is performed on a patient suffering from a heart failure (left heart failure).
More specifically, as illustrated in Fig. 6, the treatment method is performed on the patient suffering from a chronic heart failure, who has high blood pressure in a left atrium HLa due to myocardial hypertrophy appearing in a left ventricle of the heart H and increased stiffness (hardness).

[0033] As illustrated in Fig. 5, the treatment method according to the present embodiment includes a step of forming the through-hole Hh in the atrial septum HA (S1), a step of disposing the expansion body 21 in the through-hole Hh (S2), a step of enlarging the diameter of the through-hole Hh by using the expansion body 21 (S3), a step of confirming hemodynamics in the vicinity of the through-hole Hh (S4), a step of performing the maintenance treatment for maintaining the size of the through-hole Hh (S5), and a step of confirming the hemodynamics

in the vicinity of the through-hole Hh after the maintenance treatment is performed (S6).

[0034] When the through-hole Hh is formed, an operator delivers an introducer 210 in which a guiding sheath 211 and a dilator 212 are combined with each other, to the vicinity of the atrial septum HA.

For example, the introducer 210 can be delivered to a right atrium HRa via an inferior vena cava Iv.

In addition, the introducer 210 can be delivered using the guide wire 11.

The operator can insert the guide wire 11 into the dilator 212, and can deliver the introducer 210 along the guide wire 11.

The introducer 210 and the guide wire 11 can be inserted into a living body by using a known method such as using a blood vessel introducer.

[0035] In Step S1, the operator causes a puncture device (not illustrated) to penetrate from the right atrium HRa side toward the left atrium HLa side, thereby forming the through-hole Hh.

For example, a device such as a wire having a sharp distal end can be used as the puncture device.

The puncture device is inserted into the dilator 212, and is delivered to the atrial septum HA.

The puncture device can be delivered to the atrial septum HA instead of the guide wire 11 after the guide wire 11 is removed from the dilator 212.

[0036] In Step S2, the medical device 10 is first delivered to the vicinity of the atrial septum HA along the guide wire 11 inserted in advance.

At this time, the distal portion of the medical device 10 penetrates the atrial septum HA, and reaches the left atrium HLa.

In addition, when the medical device 10 is inserted, the expansion body 21 is in a state of being stored in the storage sheath 30.

[0037] The expansion body 21 is moved to the distal side in a state where the expansion body stored in the storage sheath 30 is located in the vicinity of the atrial septum HA, so that a distal side portion of the expansion body 21 is exposed inside the left atrium HLa.

In the manner, the distal side portion from the recessed portion 57 in the expansion body 21 expands in the radial direction.

Here, a distal side surface of the recessed portion 57 is pressed against a surface on the left atrium HLa side of the atrial septum HA.

In this manner, the expansion body 21 is positioned.

Next, as illustrated in Fig. 6, the storage sheath 30 is moved to the proximal side so that the whole expansion body 21 is exposed.

In the manner, the proximal side portion in the expansion body 21 expands in the radial direction inside the right atrium HRa, and the atrial septum HA is held by the recessed portion 57.

[0038] In Step S3, the operator operates the operation unit 23 in a state where the atrial septum HA is held by the recessed portion 57. In this manner, the pulling shaft 33 is moved to the proximal side.

In this manner, the expansion body 21 further expands in the radial direction to widen the held through-hole Hh in the radial direction.

[0039] After the through-hole Hh is enlarged, the hemodynamics are confirmed in Step S4.

As illustrated in Fig. 6, the operator delivers a hemodynamics confirming device 220 to the right atrium HRa by way of the inferior vena cava Iv.

For example, a known echo catheter can be used as the hemodynamics confirming device 220.

The operator can display an echo image acquired by the hemodynamics confirming device 220 on a display apparatus such as a display, and can confirm a blood volume passing through the through-hole Hh, based on a display result thereof.

[0040] Next, in Step S5, the operator performs the maintenance treatment for maintaining the size of the through-hole Hh.

In the maintenance treatment, high-frequency energy is applied to an edge portion of the through-hole Hh through the maintenance treatment element 22, thereby cauterizing (heating and cauterizing) the edge portion of the through-hole Hh by using the high-frequency energy.

When the biological tissue in the vicinity of the edge portion of the through-hole Hh is cauterized through the maintenance treatment element 22, a degenerated portion having the degenerated biological tissue is formed in the vicinity of the edge portion.

The biological tissue in the degenerated portion is in a state where elasticity is lost. Accordingly, the through-hole Hh can maintain a shape widened by the expansion body 21.

[0041] In a state where the recessed portion 57 having the maintenance treatment element 22 grips the atrial septum HA as described above, the maintenance treatment is performed.

Therefore, when the maintenance treatment is performed, the positional displacement of the maintenance treatment element 22 can be prevented.

[0042] The maintenance treatment element 22 is disposed to protrude from a surface of the recessed portion 57. Therefore, the recessed portion 57 is pressed against the atrial septum HA. In this manner, the maintenance treatment is performed in a state where the maintenance treatment element 22 is incorporated in the biological tissue.

In this manner, the maintenance treatment element 22 is prevented from coming into contact with the blood during the maintenance treatment. Accordingly, it is possible to suppress appearance of a thrombus caused by a current leaking into the blood.

[0043] After the maintenance treatment is performed, the hemodynamics are confirmed again in Step S6. In a case where the blood volume passing through the through-hole Hh reaches a desired volume, the operator decreases the diameter of the expansion body 21. After the expansion body 21 is stored in the storage sheath

30, the expansion body 21 is removed from the through-hole Hh.
Furthermore, the whole medical device 10 is removed outward of the living body, and the treatment is completed.

[Second Embodiment of Expansion body]

[0044] Next, an expansion body 60 according to a second embodiment will be described.
The expansion body 60 is used for the medical device 10 described above.
An overall configuration of the medical device 10 is the same as that of the medical device 10 described above except for the expansion body 60, and thus, description thereof will be omitted.
[0045] As illustrated in Fig. 7, the expansion body 60 has a proximal side wire portion 61 and the distal side wire portion 62, which are linked with each other by a hinge portion 63.
The hinge portion 63 is formed by combining a rotating shaft portion 63a disposed in the distal side wire portion 62 and a receiving portion 63b disposed in the proximal side wire portion 61 with each other.
The hinge portion 63 links the proximal side wire portion 61 and the distal side wire portion 62 with each other to be pivotable.
[0046] As illustrated in Fig. 8, the distal side wire portion 62 has a projection portion 62a in the distal portion.
The rotating shaft portion 63a is disposed to extend outward from both sides of the projection portion 62a.
The proximal side wire portion 61 has a recess portion 61a for storing the projection portion 62a.
The recess portion 61a has a receiving portion 63b that receives the rotating shaft portion 63a to be rotatable.
[0047] The projection portion 62a of the distal side wire portion 62 and the recess portion 61a of the proximal side wire portion 61 are attached to each other in the circumferential direction of the expansion body 60.
In this manner, the proximal side wire portion 61 and the distal side wire portion 62 are restricted in moving relative to each other in the circumferential direction. Therefore, it is possible to suppress torsion of the expansion body 60 in the circumferential direction.
That is, the hinge portion 63 functions as the torsion restriction portion of the expansion body 60.
[0048] As illustrated in Fig. 9, the operation unit 23 is operated to move the pulling shaft 33 to the proximal side. In this manner, the hinge portion 63 pivots, and the expansion body 60 expands in the radial direction.
In this manner, the through-hole Hh of the atrial septum HA can be enlarged.
[0049] In this example, the receiving portion 63b is disposed in the proximal side wire portion 61, and the rotating shaft portion 63a is disposed in the distal side wire portion 62, respectively. However, the rotating shaft portion 63a may be disposed in the proximal side wire portion 61, and the receiving portion 63b may be disposed in the distal side wire portion 62, respectively.
In addition, in this example, the recess portion 61a is disposed in the proximal side wire portion 61, and the projection portion 62a is disposed in the distal side wire portion 62. However, the projection portion may be disposed in the proximal side wire portion 61, and the recess portion may be disposed in the distal side wire portion 62, respectively.
[0050] A modification example of the expansion body having the hinge portion will be described.
As illustrated in Fig. 10, the expansion body 64 may have a recessed portion 65 formed by the proximal side wire portion 61 and the distal side wire portion 62.
In this case, an edge portion of the recessed portion 65 has an elastically deformable shape which is thinner than the other portions, and the hinge portion 63 is disposed in a bottom portion of the recessed portion 65.
As illustrated in Fig. 11, the expansion body 64 expands. Accordingly, in the recessed portion 65, the hinge portion 63 pivots to hold the atrial septum HA, and elastically deforms so that an angle of an edge portion further decreases.
In this manner, the recessed portion 65 is further narrowed, and the force of holding the biological tissue can be increased.
[0051] As illustrated in Fig. 12, the expansion body 66 may have three hinge portions.
In this case, the recessed portion 67 is formed by the proximal side wire portion 61 and the distal side wire portion 62.
The hinge portion 63 is disposed in the bottom portion of the recessed portion 67.
In addition, a second hinge portion 68 and a third hinge portion 69 are respectively disposed on both sides of the recessed portion 67.
In this manner, as illustrated in Fig. 13, when the pulling shaft 33 is moved to the proximal side, the hinge portion 63, the second hinge portion 68, and the third hinge portion 69 respectively pivot to increase the diameter of the expansion body 66. The recessed portion 67 is narrowed so that the force of holding the biological tissue can be increased.
In addition, a plurality of the hinge portions are provided. Accordingly, a restriction force in the circumferential direction of the proximal side wire portion 61 and the distal side wire portion 62 can be increased, and it is possible to further suppress the torsion of the expansion body 66.

[Third Embodiment of Expansion body]

[0052] Next, an expansion body 70 according to a third embodiment will be described.
The expansion body 70 is used for the medical device 10 described above.
An overall configuration of the medical device 10 is the same as that of the medical device 10 described above except for the expansion body 70, and thus, description thereof will be omitted.

[0053] As illustrated in Fig. 14, the expansion body 70 has a proximal side wire portion 71 and a distal side wire portion 72.

The central portion of the expansion body 70 has a fitting portion 73 in which the proximal side wire portion 71 and the distal side wire portion 72 are linked to support each other.

[0054] As illustrated in Fig. 15(a), the proximal side wire portion 71 has a recess portion 71a which serves as an insertion portion in the distal portion.

The recess portion 71a has a linear bottom edge portion 71b.

In addition, as illustrated in Fig. 15(b), the distal side wire portion 72 has a projection portion 72a in the distal portion.

Both side linear edge portions 72b are formed in a root portion of the projection portion 72a.

[0055] As illustrated in Fig. 15(c), the projection portion 72a of the distal side wire portion 72 is inserted into the recess portion 71a of the proximal side wire portion 71. In this manner, the bottom edge portion 71b of the proximal side wire portion 71 and the distal side wire portion 72 are attached to each other, and the proximal side wire portion 71 and the both side edge portions 72b of the distal side wire portion 72 are attached to each other.

The recess portion 71a and the projection portion 72a are fitted together, thereby forming the fitting portion 73 in which the proximal side wire portion 71 and the distal side wire portion 72 are linked to support each other.

[0056] The projection portion 72a has the width substantially the same as that of the recess portion 71a. Accordingly, the proximal side wire portion 71 and the distal side wire portion 72 are attached to each other in the circumferential direction of the expansion body 70. In this manner, both of these are restricted in moving in the circumferential direction.

That is, the fitting portion 73 functions as the torsion restriction portion that restricts the movement of the proximal side wire portion 71 and the distal side wire portion 72 in the circumferential direction of the expansion body 70.

[0057] As illustrated in Fig. 16, the expansion body 70 expands by operating the operation unit 23 to move the pulling shaft 33 to the proximal side.

The proximal side wire portion 71 and the distal side wire portion 72 support each other in a fitting element, and are not fixed to each other. Accordingly, the diameter can be increased while an angle formed between both of these is changed.

The angle formed between the distal portion of the proximal side wire portion 71 and the distal portion of the distal side wire portion 72 decreases due to the expansion of the expansion body 70.

Therefore, the atrial septum HA can be held by this portion.

[0058] In the expansion body 70, the proximal side wire portion 71 has the recess portion 71a, and the distal side wire portion 72 has the projection portion 72a, respectively. However, the distal side wire portion 72 may have the recess portion, and the proximal side wire portion 71 may have the projection portion, respectively.

[0059] In addition, in a form of the expansion body 70 illustrated in Fig. 14, a shape other than the recess portion 71a and the projection portion 72a can be adopted as a shape in which the proximal side wire portion 71 and the distal side wire portion 72 are linked with each other.

As illustrated in Fig. 17, the proximal side wire portion 71 and the distal side wire portion 72 may respectively have cutout portions 71c and 72c, and both of these may be fitted together.

[0060] In addition, as illustrated in Fig. 18, the proximal side wire portion 71 may have a thin portion 71d. The distal side wire portion 72 may have an insertion portion 72d formed using a slit hole, and the thin portion 71d may be inserted into the insertion portion 72d.

Contrary to Fig. 18, the distal side wire portion 72 may have the thin portion, and the proximal side wire portion 71 may have the insertion portion.

[0061] A modification example of the expansion body having the fitting portion will be described.

As illustrated in Fig. 19, an expansion body 80 has a proximal side wire portion 83 and a distal side wire portion 84.

In the proximal side wire portion 83, a link portion 83a of the proximal end is fixed to a proximal portion 81 of the expansion body 80, and in the distal side wire portion 84, a link portion 84a of the distal end is fixed to a distal portion 82 of the expansion body 80, respectively.

[0062] The proximal side wire portion 83 has a large-diameter portion 83b inclined so that the diameter increases from the link portion 83a toward the distal side in the radial direction of the expansion body 80, a bending portion 83c bent inward in the radial direction of the expansion body 80, an extension portion 83e extending toward the distal side from a portion intersecting the distal side wire portion 84, and a fixed portion 83f fixed by being attached to the link portion 84a of the distal side wire portion 84.

The distal side wire portion 84 has a shape obtained by inverting the proximal side wire portion 83, and has a large-diameter portion 84b, a bending portion 84c, an extension portion 84e, and a fixed portion 84f.

[0063] As illustrated in Fig. 20, the distal side wire portion 84 has an insertion portion 84d formed using a slit hole in the bending portion 84c, and the proximal side wire portion 83 has a thin portion 83d inserted into an insertion portion 84d.

The proximal side wire portion 83 supports the distal side wire portion 84 in an end portion of the extension portion 83e, and the distal side wire portion 84 supports the proximal side wire portion 83 in an end portion of the insertion portion 84d.

In this way, an intersection portion between the proximal side wire portion 83 and the distal side wire portion 84 has a fitting portion 85 in which both of these support each other.

The width of the thin portion 83d is substantially the same as the width of the insertion portion 84d. Accordingly, the proximal side wire portion 83 and the distal side wire portion 84 are restricted in moving relative to each other in the circumferential direction of the expansion body 80. That is, the fitting portion 85 functions as the torsion restriction portion that restricts the movement of the proximal side wire portion 83 and the distal side wire portion 84 in the circumferential direction of the expansion body 80.

[0064] In a case where the proximal side wire portion 83 and the distal side wire portion 84 are extended, the thin portion 83d is stored inside the insertion portion 84d. Accordingly, both of these can have a linear shape without interfering with each other.

In this manner, the expansion body 80 can be stored inside the storage sheath 30.

[0065] As illustrated in Fig. 21, the pulling shaft 33 is moved to the proximal side. Accordingly, the proximal side wire portion 83 and the distal side wire portion 84 which support each other can deform in a diameter increasing direction, and the diameter of the expansion body 80 can be increased.

In this case, the torsion of the expansion body 80 in the circumferential direction is suppressed by the fitting portion 85 serving as the torsion restriction portion.

[0066] In the expansion body 80, the proximal side wire portion 83 has the thin portion 83d, and the distal side wire portion 84 has the insertion portion 84d, respectively. However, the distal side wire portion 84 may have thin portion, and the proximal side wire portion 83 may have the insertion portion, respectively.

[0067] An expansion body 90 according to still another modification example will be described.

As illustrated in Fig. 22, the expansion body 90 has a proximal side wire portion 93 and a distal side wire portion 94 which respectively have a loop shape.

The proximal side wire portion 93 is fixed to a proximal portion 91 of the expansion body 90, and the distal side wire portion 94 is fixed to a distal portion 92 of the expansion body 90, respectively.

The proximal side wire portion 93 and the distal side wire portion 94 are linked with each other by a link portion 96 such as a wire.

The link portion 96 is provided to maintain a positional relationship between the proximal side wire portion 93 and the distal side wire portion 94 when the expansion body 90 is stored in the storage sheath 30.

[0068] As illustrated in Fig. 23(a), the proximal side wire portion 93 and the distal side wire portion 94 are linked with by the link portion 96, and both of these are not directly fixed to each other.

As illustrated in Fig. 23(b), the proximal side wire portion 93 and the distal side wire portion 94 move close to each other to intersect each other. In this manner, both of these are in a state of supporting each other.

[0069] As illustrated in Fig. 24, the proximal side wire portion 93 has an insertion portion 93a formed using a slit hole, and the distal side wire portion 94 has a thin portion 94a inserted into an insertion portion 93a.

The thin portion 94a can be inserted into the insertion portion 93a, and both of these form a fitting portion 95. The insertion portion 93a and the thin portion 94a are fitted together. Accordingly, the proximal side wire portion 93 and the distal side wire portion 94 support each other. In the fitting portion 95, both sides of the thin portion 94a are attached to the insertion portion 93a. Accordingly, the proximal side wire portion 93 and the distal side wire portion 94 are attached to each other in the fitting portion 95 in the circumferential direction. In this manner, the fitting portion 95 can function as the torsion restriction portion.

[0070] As described above, according to the above-described embodiment, there is provided the medical device 10 which enlarges the biological tissue. The medical device 10 includes the elongated shaft portion 20, and the expansion body 21 disposed in the distal portion of the shaft portion 20, and configured to expand and contract in the radial direction. The expansion body 21 has the wire portion 50 linked with the shaft portion 20, and the torsion restriction portion that restricts the movement of the wire portion 50 in the circumferential direction. In this manner, it is possible to suppress the torsion of the expansion body 21 when the expansion body 21 formed using the wire expands in the circumferential direction.

[0071] In addition, when a plurality of the wire portions 50 are disposed in the circumferential direction and the torsion restriction portion is configured so that the wire portions 50 adjacent to each other in the circumferential direction of the expansion body 21 are connected to each other, since the wire portions 50 are connected to each other in the circumferential direction, it is possible to reliably suppress the torsion of the expansion body 21.

[0072] In addition, when the wire portion 50 has the bifurcated portion 53 bifurcated into the two bifurcated lines 54 and the bifurcated line 54 bifurcated from one of the wire portions 50 merges with the bifurcated line 53 bifurcated from an adjacent wire portion 50, a force is easily transmitted in the axial direction, and it is possible to achieve the expansion body 21 which can suppress the torsion in the circumferential direction.

[0073] In addition, when the proximal side and the distal side of the expansion body 21 respectively have the bifurcated lines 54 and the central wire portions 56 where the bifurcated lines 54 merge with each other are respectively disposed on both sides in the length direction between the bifurcated lines 54 on the proximal side and the distal side, it is possible to suppress the torsion in the circumferential direction on both sides of the central portion of the expansion body 21 that transmits the expansion force to the biological tissue.

[0074] In addition, when the central wire portion 56 has the recessed portion 57 recessed in the direction orthogonal to the axial direction of the expansion body 21, when the expansion body 21 expands, the biological tissue can be easily held by the recessed portion 57.

[0075] In addition, when the torsion restriction portion links the proximal side wire portion 61 and the distal side wire portion 62 with each other and the linked wire portions 61 and 62 are attached to each other in the circumferential direction, the wire portions 61 and 62 support each other in the circumferential direction. Accordingly, it is possible to suppress the torsion of the expansion body 60.

[0076] In addition, when the torsion restriction portion has the rotating shaft portion 63a disposed in one of the wire portions 62 and the receiving portion 63b disposed in the other of the wire portions 61 and receiving the rotating shaft portion 63a to be rotatable, the proximal side wire portion 61 and the distal side wire portion 62 can freely pivot relative to each other. Accordingly, the expansion body 60 easily expands in the radial direction, and the mutual movement in the circumferential direction is restricted in a rotating portion.

[0077] In addition, when the expansion body 64 has the recessed portion 65 in the intermediate portion in the axial direction and the torsion restriction portion is disposed in at least the bottom portion of the recessed portion 65, the recessed portion 65 is likely to deform. Accordingly, the biological tissue is held by the recessed portion 65, and it is possible to suppress the positional displacement of the expansion body 64.

[0078] In addition, when the torsion restriction portion is the fitting portion 73 in which the proximal side wire portion 71 and the distal side wire portion 72 are linked to support each other, the wire portions 71 and 72 support each other so that the torsion in the circumferential direction can be suppressed.

[0079] In addition, when one of the proximal side wire portion 83 and the distal side wire portion 84 has the insertion portion 84d formed using the slit hole or the cutout portion into which the other wire portion 83 is inserted and the other wire portion 83 is supported by the end portion of the insertion portion 84d, the wire portions 83 and 84 intersect and support each other in the axial direction of the expansion body 80. Accordingly, the torsion in the circumferential direction is suppressed in an intersection portion.

[0080] In addition, when the wire portion 50 has the maintenance treatment element 22 that performs the maintenance treatment on the biological tissue, the expansion body 21 can expand without any torsion. Accordingly, the maintenance treatment element 22 can be reliably brought into pressing contact with the biological tissue, and the energy can be accurately applied to the target site of the biological tissue.

[0081] The present invention is not limited to the above-described embodiments, and various modifications can be made by those skilled in the art within the technical idea of the present invention.

[0082] This application is based upon and claims the benefit of priority from Japanese Patent Application No. 2018-064007, filed on March 29, 2018, the entire contents of which are incorporated herein by reference.

Reference Signs List

[0083]

10	medical device
11	guide wire
20	shaft portion
21	expansion body
22	maintenance treatment element
23	operation unit
30	storage sheath
31	outer shaft
33	pulling shaft
35	distal member
40	housing
41	operation dial
42	conversion mechanism
50	wire portion
53	bifurcated portion
54	bifurcated line
55	merging portion
56	central wire portion
57	recessed portion

Claims

1. A medical device configured to enlarge a biological tissue, comprising:

   an elongated shaft portion; and
   an expansion body disposed in a distal portion of the shaft portion, and configured to expand and contract in a radial direction,
   wherein the expansion body has a wire portion linked with the shaft portion, and a torsion restriction portion that is configured to restrict movement of the wire portion in a circumferential direction.

2. The medical device according to Claim 1,
   wherein a plurality of the wire portions are disposed in the circumferential direction, and the torsion restriction portion connects the wire portions adjacent to each other in the circumferential direction of the expansion body.

3. The medical device according to Claim 2,
   wherein the wire portions have a bifurcated portion bifurcated into two bifurcated lines, and the bifurcated line bifurcated from one of the wire portions merges with the bifurcated line bifurcated from an adjacent wire portion to serve as the torsion restriction portion.

4. The medical device according to Claim 3,
   wherein the expansion body has each of the bifurcated lines on a proximal side and a distal side, and

a central wire portion in which the bifurcated lines respectively merge with each other on both sides in a length direction is provided between the bifurcated lines on the proximal side and the distal side.

5. The medical device according to Claim 4, wherein the central wire portion includes a recessed portion having a recessed shape in a direction orthogonal to an axial direction of the expansion body.

6. The medical device according to Claim 1, wherein the torsion restriction portion links the wire portion on the proximal side and the wire portion on the distal side with each other, and the linked wire portions are attached to each other in the circumferential direction.

7. The medical device according to Claim 4, wherein the torsion restriction portion has a rotating shaft portion disposed in one of the wire portions, and a receiving portion disposed in the other of the wire portions and receiving the rotating shaft portion to be rotatable.

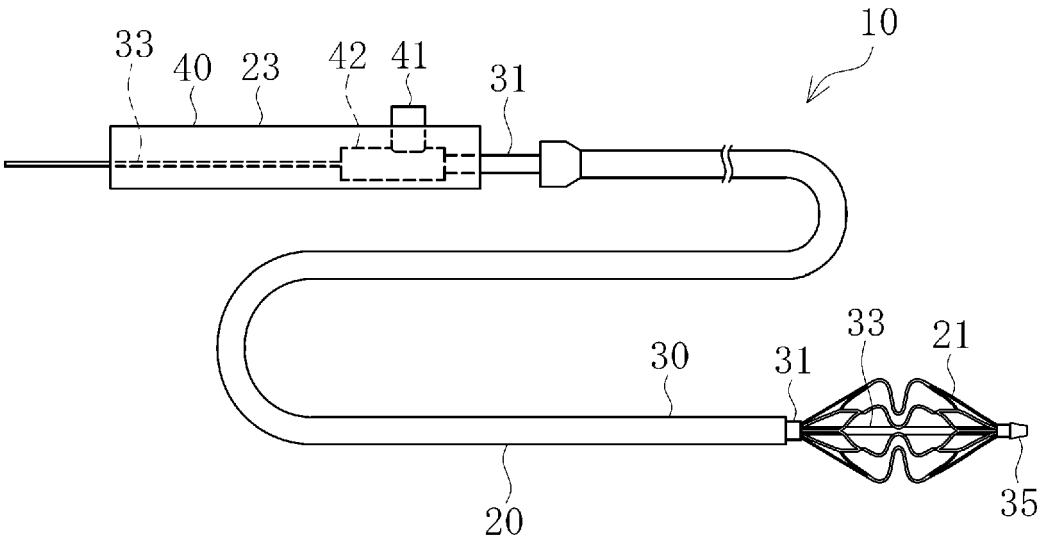
8. The medical device according to Claim 4 or 5, wherein the expansion body has a recessed portion in an intermediate portion in an axial direction, and the torsion restriction portion is disposed in at least a bottom portion of the recessed portion.

9. The medical device according to Claim 4, wherein the torsion restriction portion is a fitting portion in which the wire portion on the proximal side and the wire portion on the distal side are linked to support each other.

10. The medical device according to Claim 7, wherein one of the wire portion on the proximal side and the wire portion on the distal side has an insertion portion formed to have a slit hole or a cutout portion into which the other of the wire portions is inserted, and the other of the wire portions is supported by an end portion of the insertion portion.

11. The medical device according to any one of Claims 1 to 8, wherein the wire portion includes a maintenance treatment element that is configured to perform a maintenance treatment on a biological tissue.

[Fig. 1]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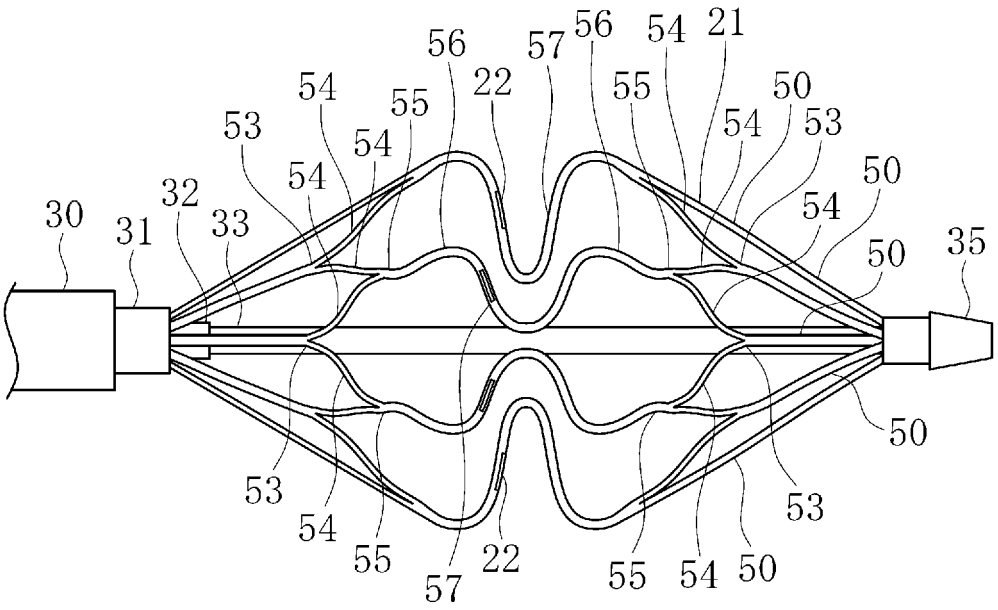
[Fig. 2]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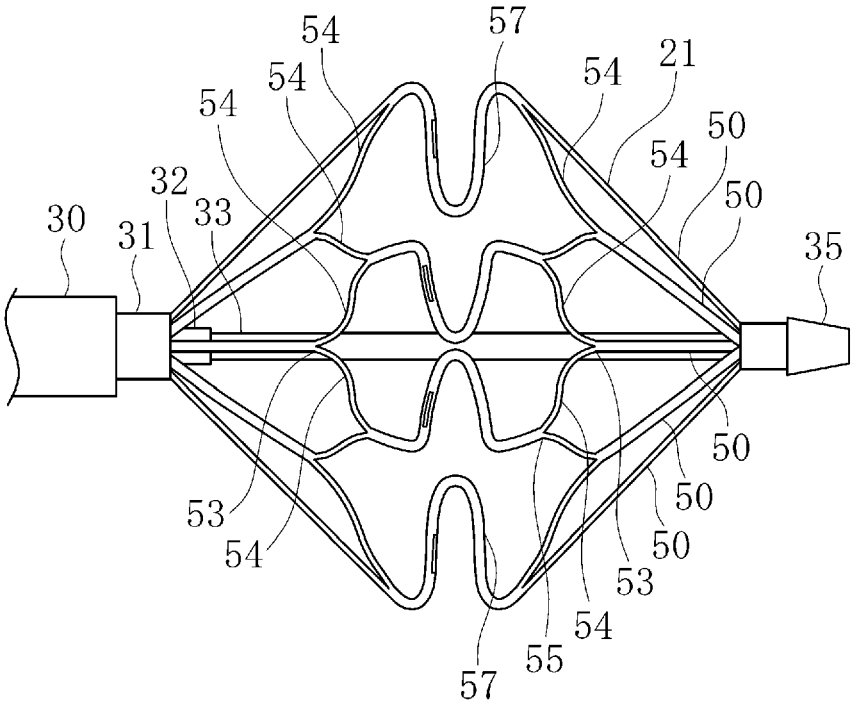
[Fig. 3]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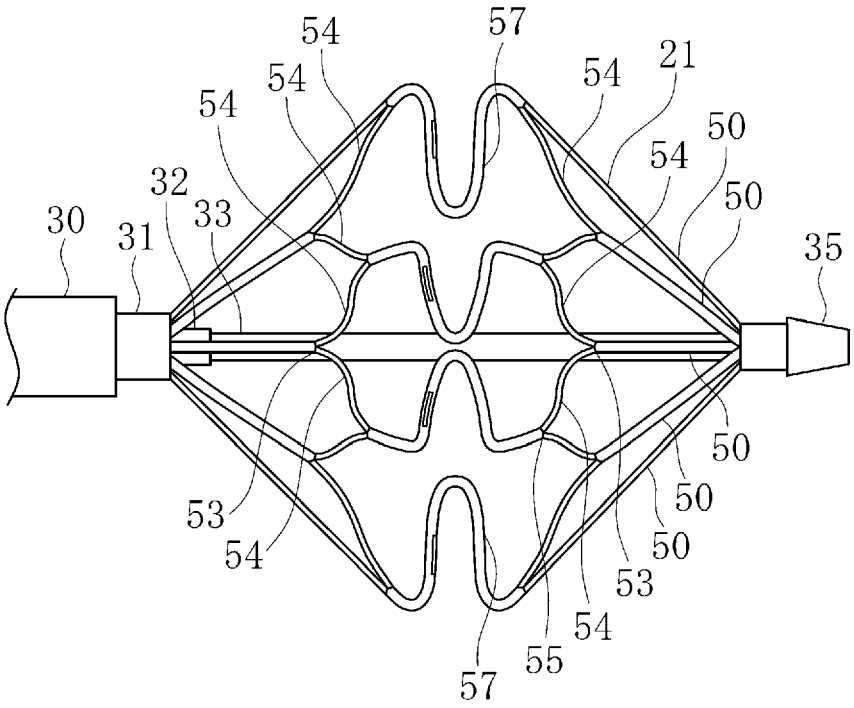
[Fig. 4]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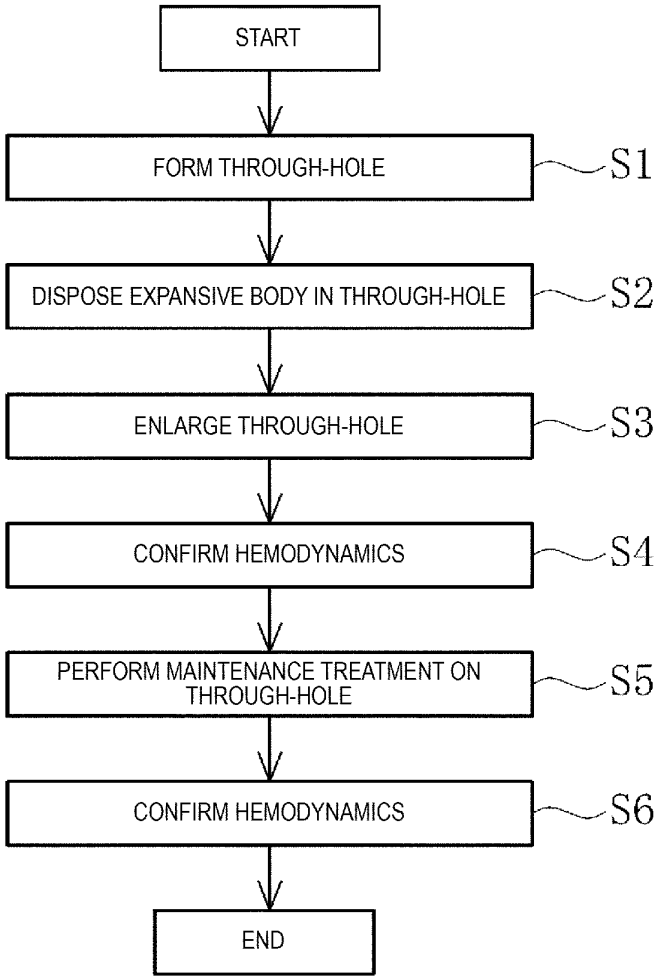
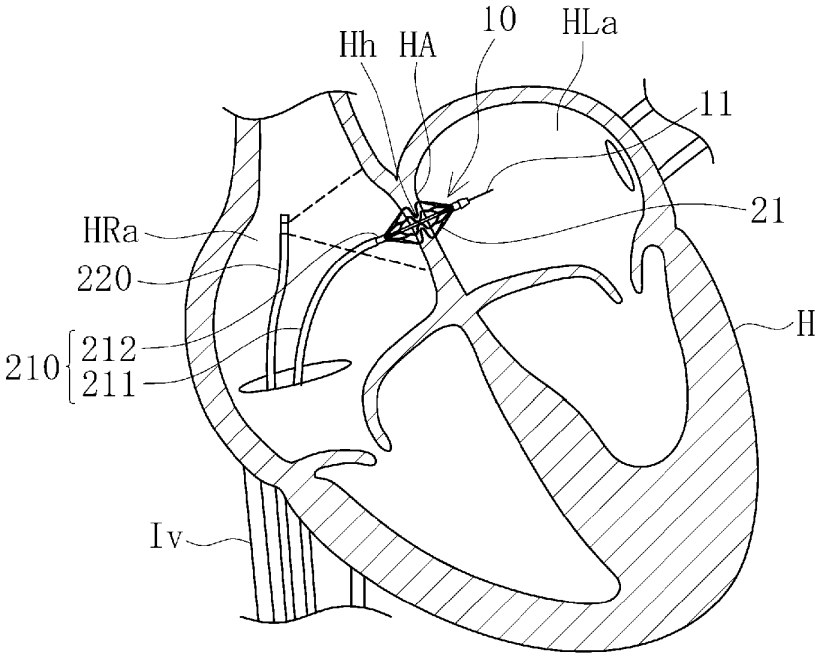
[Fig. 5]


START
FORM THROUGH-HOLE
S1
DISPOSE EXPANSIVE BODY IN THROUGH-HOLE
S2
ENLARGE THROUGH-HOLE
S3
CONFIRM HEMODYNAMICS
S4
PERFORM MAINTENANCE TREATMENT ON THROUGH-HOLE
S5
CONFIRM HEMODYNAMICS
S6
END

[Fig. 6]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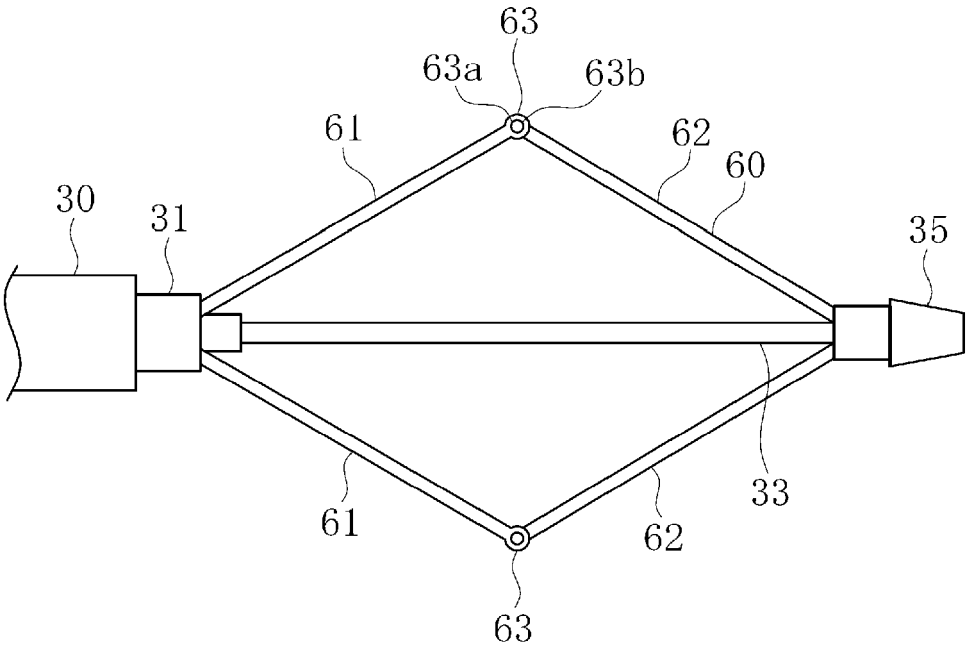
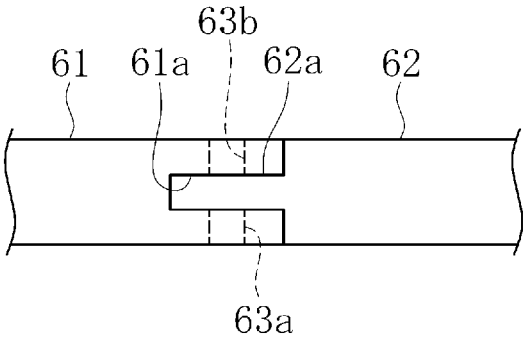
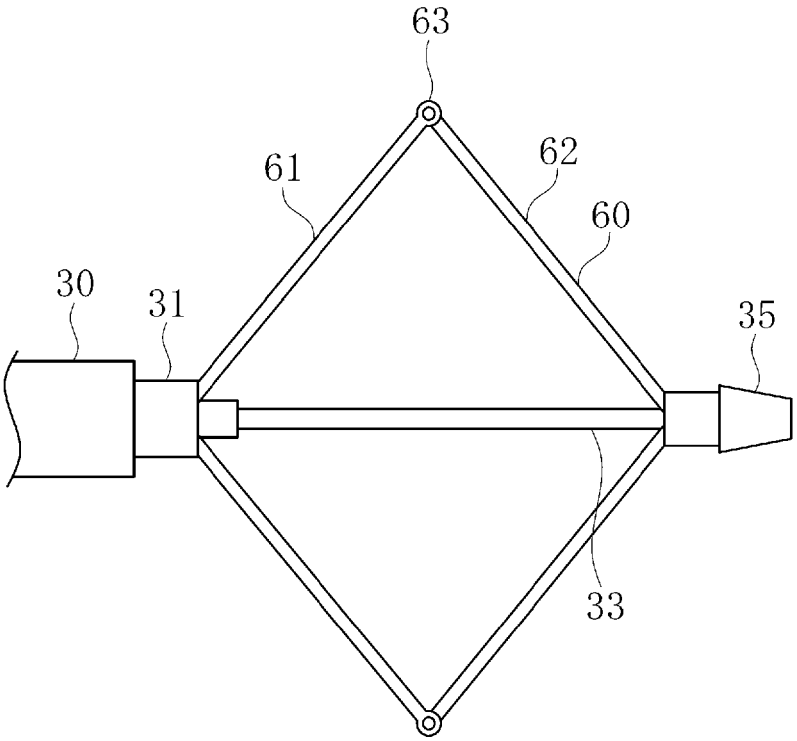
[Fig. 7]



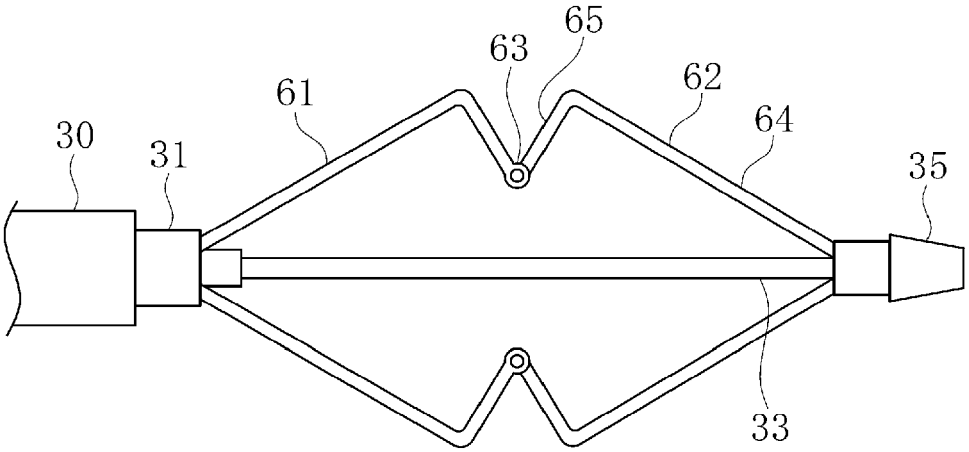
[Fig. 8]



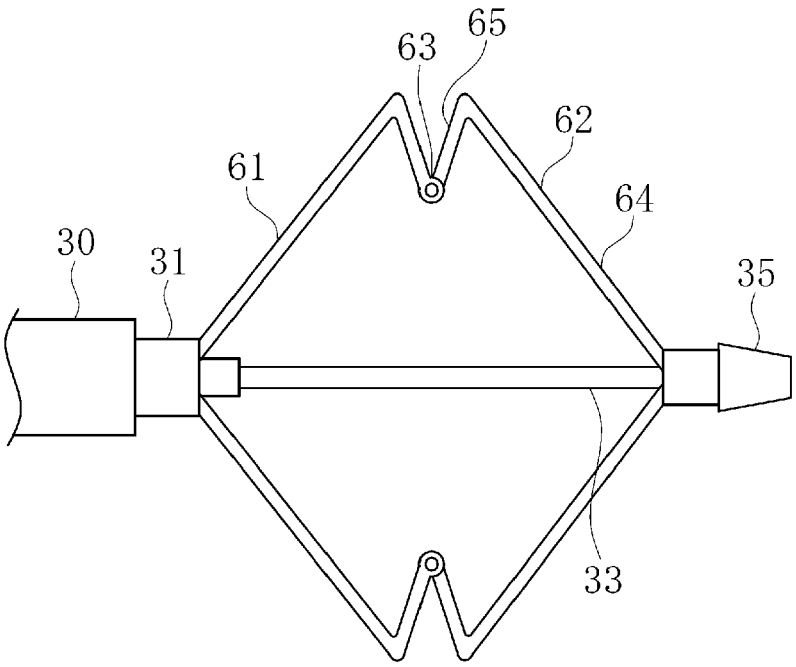
[Fig. 9]



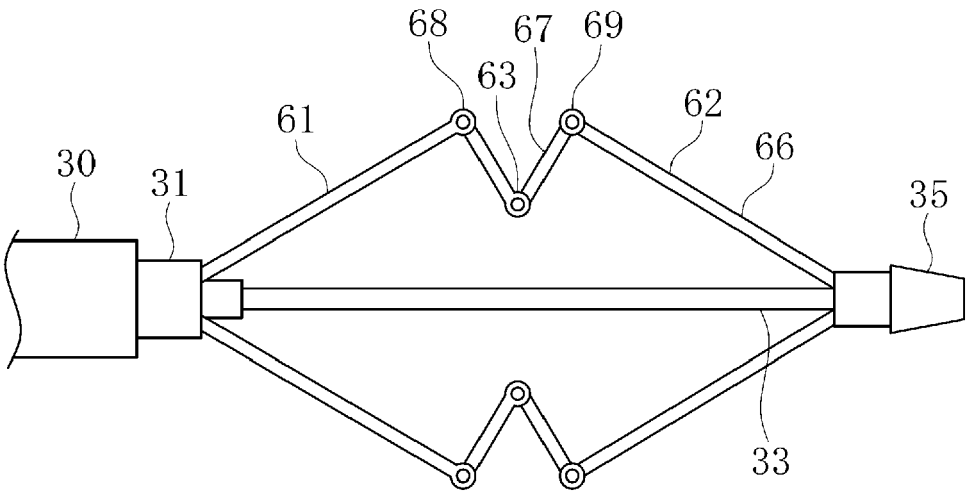
[Fig. 10]



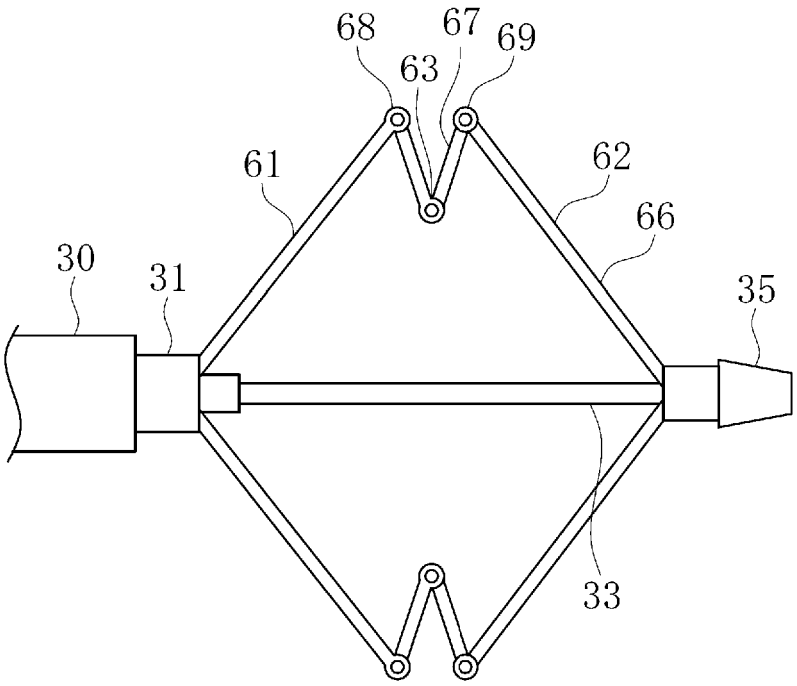
[Fig. 11]



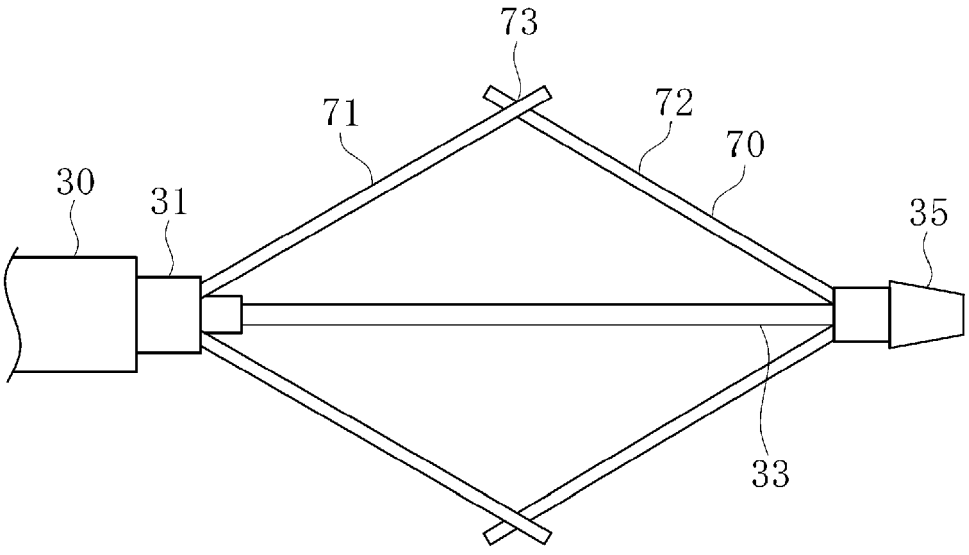
[Fig. 12]



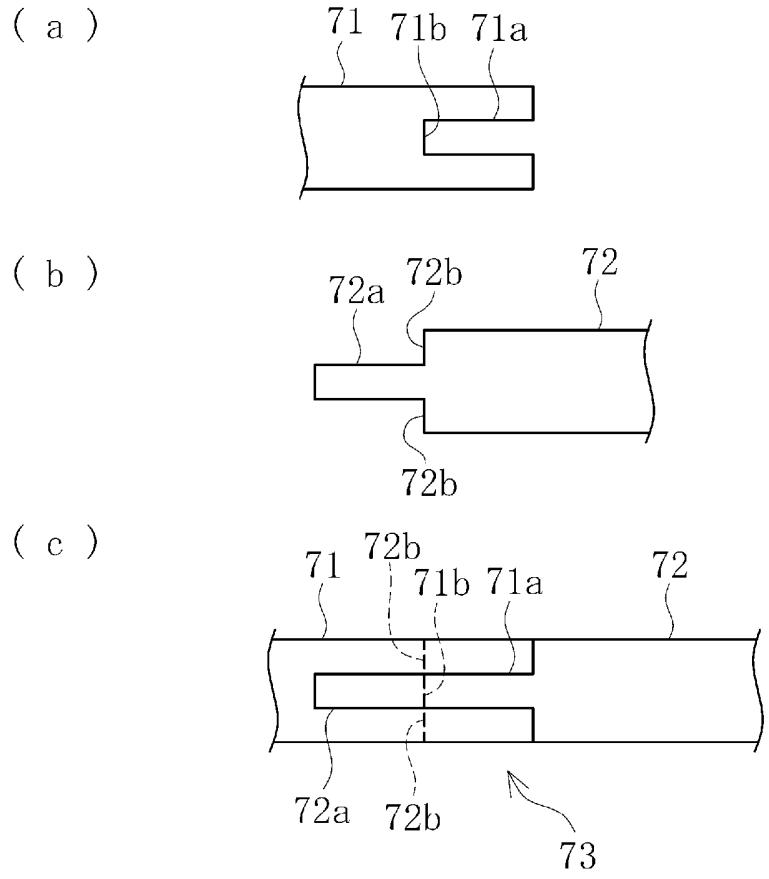
[Fig. 13]



[Fig. 14]



[Fig. 15]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71b
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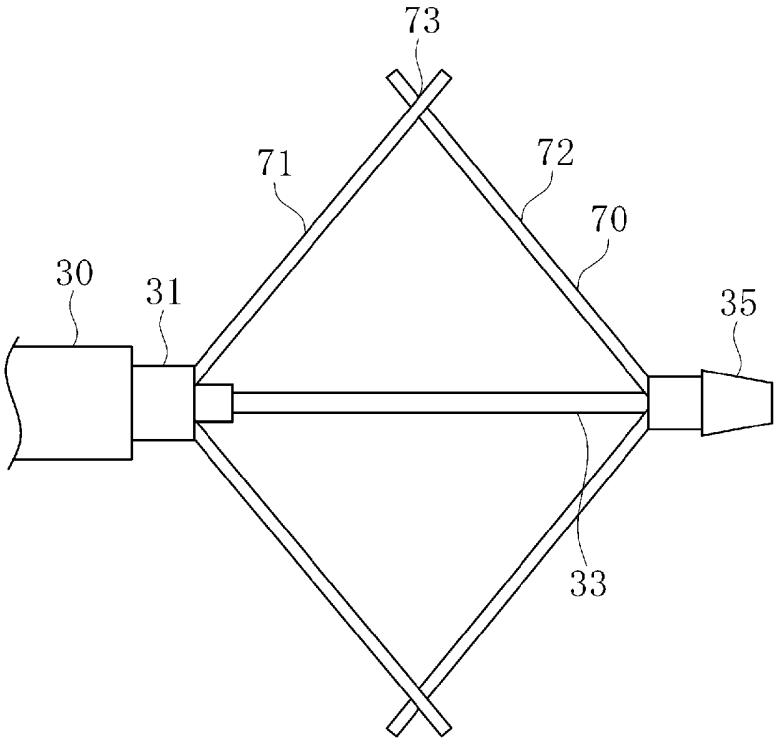
[Fig. 16]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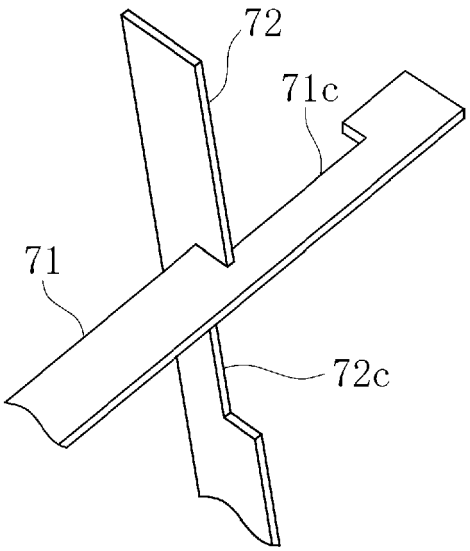
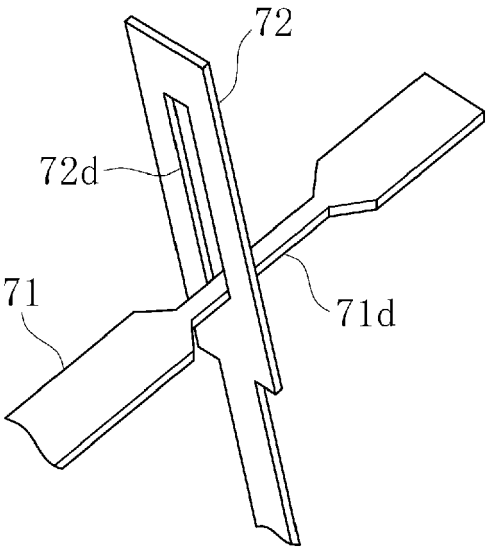
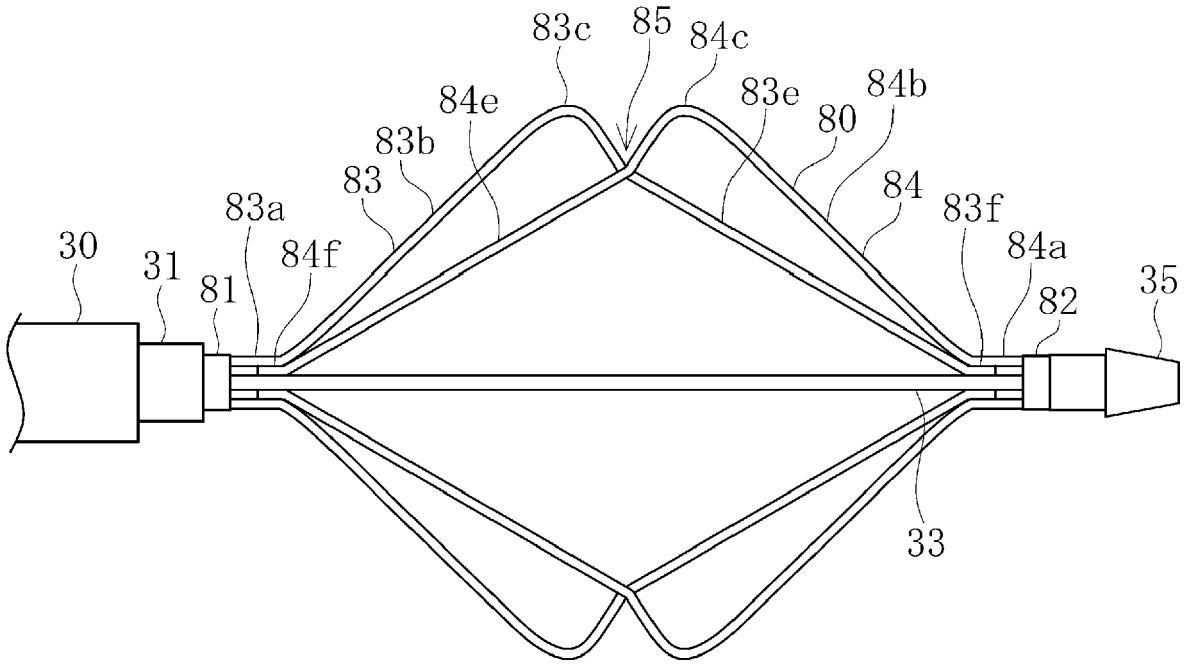
[Fig. 17]



[Fig. 18]



[Fig. 19]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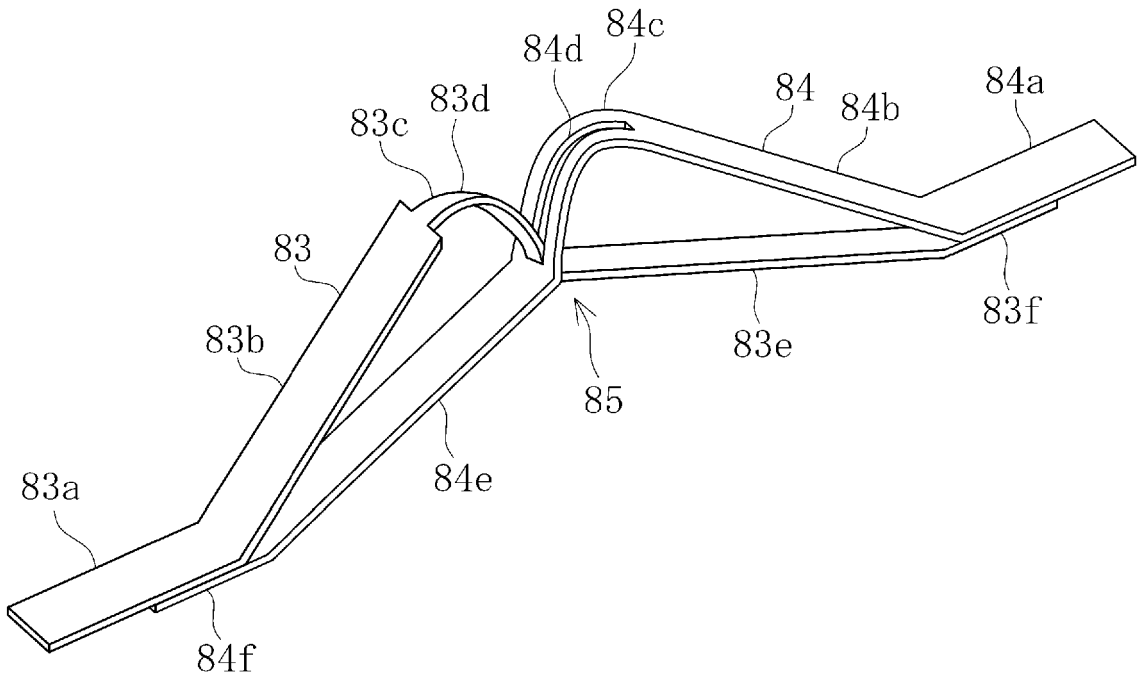
[Fig. 20]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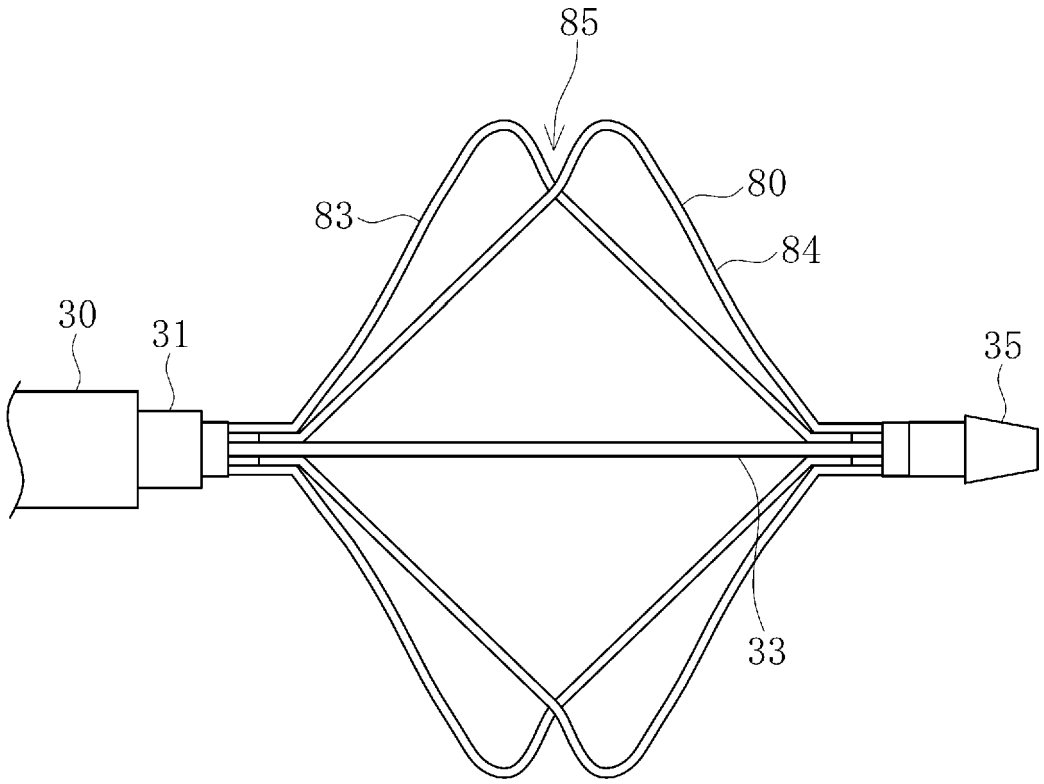
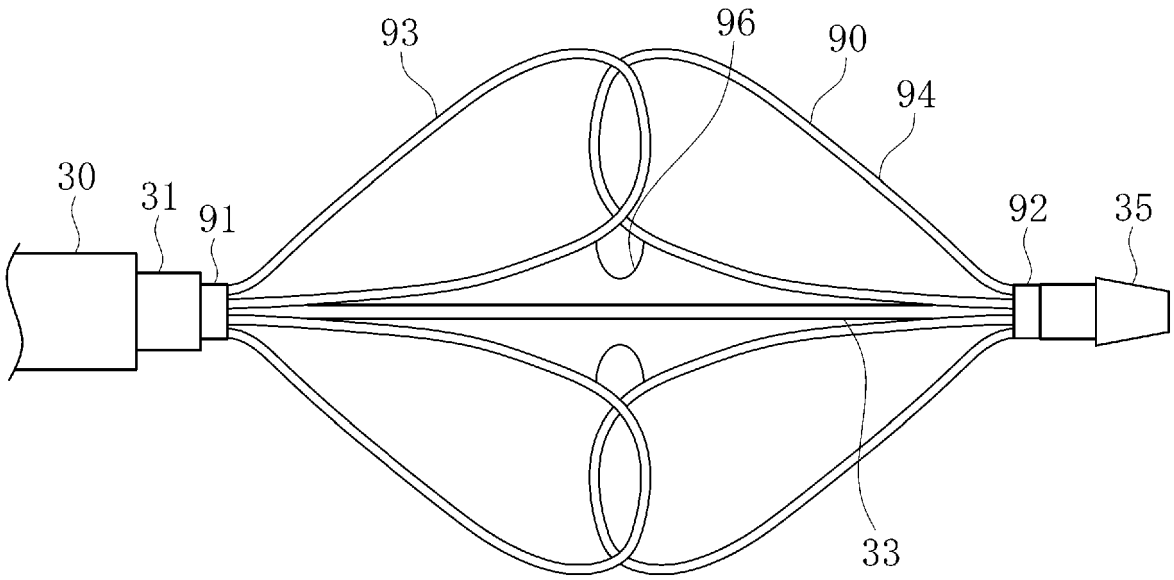
[Fig. 21]



[Fig. 22]



[Fig. 23]

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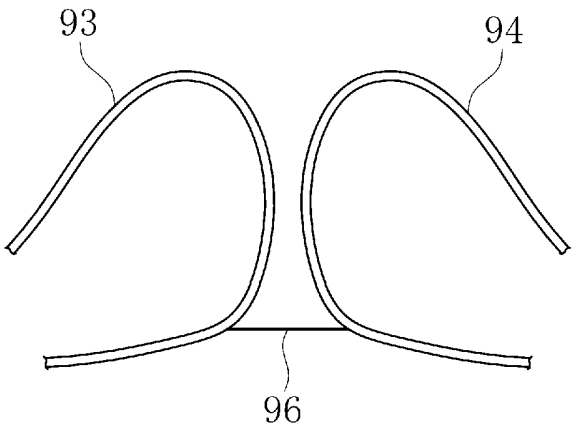

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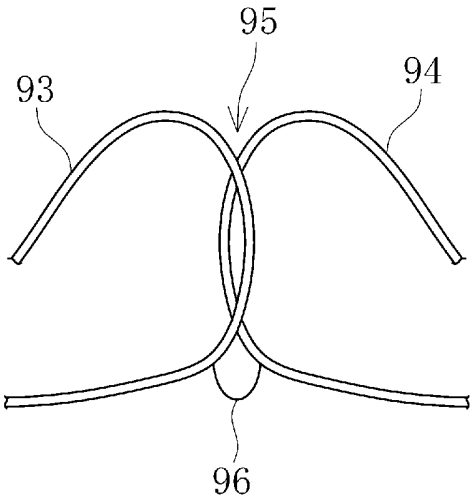
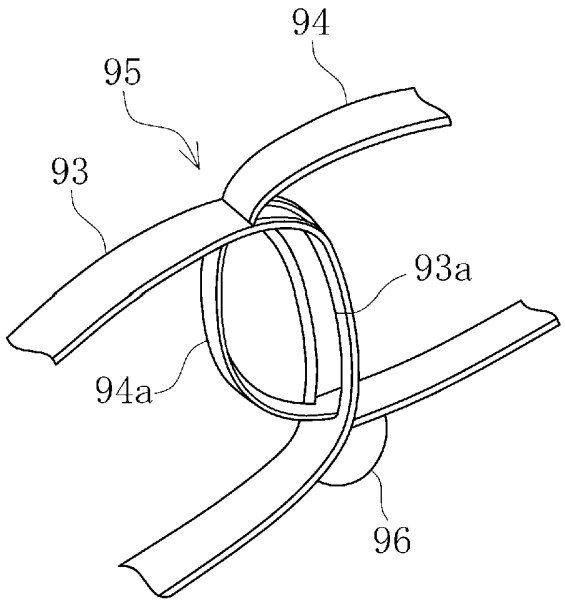


[Fig. 24]



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2019/012384

A. CLASSIFICATION OF SUBJECT MATTER
Int.Cl. A61B18/12(2006.01)i, A61B17/00(2006.01)i, A61B18/18(2006.01)i, A61B18/20(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Int.Cl. A61B18/12, A61B17/00, A61B18/18, A61B18/20

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Published examined utility model applications of Japan	1922-1996
Published unexamined utility model applications of Japan	1971-2019
Registered utility model specifications of Japan	1996-2019
Published registered utility model applications of Japan	1994-2019

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	JP 2012-50538 A (TERUMO CORPORATION) 15 March 2012, paragraphs [0051]-[0070], fig. 11-15 (Family: none)	1-6, 11 7-10

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
22.04.2019	14.05.2019

Name and mailing address of the ISA/	Authorized officer
Japan Patent Office 3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan	Telephone No.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2019/012384

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	JP 2009-512521 A (NMT MEDICAL, INC.) 26 March 2009, paragraphs [0037]-[0039], [0069]-[0071], fig. 2A-2D & US 2007/0118176 A1, paragraphs [0053]-[0055], [0085]-[0087] & WO 2007/120186 A2	1-5, 11 6-10
Y A	US 5853422 A (HUEBSCH, J.) 29 December 1998, column 3, line 39 to column 5, line 21, fig. 1-5 & US 6024756 A	1, 6, 11 2-5, 7-10

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REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 8882697 B **[0004]**
- JP 2018064007 A **[0082]**